

### **Remarks**

#### **Brief Summary:**

Setting all legal jargon aside, Berkow basically identifies allergens by way of a skin prick test or an elimination diet. Evans is for a computerized medical records system that automatically checks for drug errors, etc. The applicant provides a method that can help identify a person's allergies without a skin prick test and without an elimination diet.

By this amendment, applicant's Claim 2 has been canceled and its elements have been incorporated into Claim 1. Claim 1 has been amended to correct a grammatical error regarding antecedence. Although a "useful, concrete and tangible result" inherently flowed from original Claim 1, the applicant, nonetheless, has further amended Claim 1 to explicitly recite that "useful, concrete and tangible result." The "entering" steps of Claim 1 have been deleted to define the invention more concisely. Various dependent claims have been amended primarily due to the amendment of Claim 1. Claims 32 and 33 have been amended for reasons similar to that of Claim 1. Claims 1 and 3 – 33 remain in the application.

In rejecting the claims, the Examiner has organized the rejections, reasons and comments by way of sections labeled 3, 3A – 3D, 5, 5A – 5E, 8, and 8A, thus the applicant will follow this same outline in responding to each point of rejection.

#### **Detailed Remarks:**

3, 3A) The Examiner has rejected Claims 1-8 and 10-33 under 35 USC 101 for being directed to non-statutory subject matter. The Examiner states that the claims fail to produce any physical transformation or a useful, concrete and tangible result.

In response to this rejection, the applicant has amended Claims 1 and 32 to explicitly recite the useful, concrete and tangible result, which specifically is "identifying and displaying the suspect influencing agent." This result can repeatedly provide the practical purpose of helping individuals identify a suspect influencing agent among

numerous possible influencing agents. The claimed method might be used, for example, to help an individual identify a food that is causing an allergic reaction.

3B) The useful, concrete and tangible result of Claims 2-8 and 10-31 is recited in amended Claim 1.

3C) To overcome the rejection, Claim 32 has been amended to explicitly recite the useful, concrete and tangible result in a manner similar to that of Claim 1.

3D) The Examiner states that Claim 33 does not recite displaying the reaction's magnitude, thus the claim fails to produce any useful, concrete and tangible result.

The applicant, however, submits that Claim 33 as originally written already explicitly recites a useful, concrete and tangible result, namely, "plotting a graph of the suspect influencing agent and the reaction versus time, and displaying the graph on the computer display to help illustrate how well the suspect influencing agent and the reaction correlate." This is somewhat similar to the practical purpose recited in Claims 1 and 32 but in a graphical format. The reaction's calculated magnitude value, which is not necessarily displayed, can be used internally to help calculate the correlations and ultimately create the graph.

5, 5A-5C) The Examiner points out several instances of "the plurality of possible influencing agents" lacking antecedent basis. In response, the applicant has amended the claims according.

5D) Claim 13 has been amended to clarify that the first computation and the second computation are different with reference to a menstrual period (e.g., see item 86 of Figures 4 and 5).

5E) In Claim 32, the Examiner points out that the phrase, "the plurality of possible influencing agents" lacks antecedent basis. In response, the applicant has amended the claim according.

8, 8A) Claims 1-4, 7, 12, and 14-29 have been rejected under 35 USC 103(a) as being unpatentable over Verkow et al., THE MERCK MANUAL in view of Evans et al., A COMPUTER ASSISTED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS. The Examiner states that it would have been obvious to one of ordinary skill in the art to include the features of Evans in the method of Berkow with the motivation of providing patient data at the point-of-care. The applicant, however, disagrees with the rejection for the following reasons:

- Regarding Claim 1, Berkow in some cases appears to identify an allergen based on a skin prick test and then validates the test results by seeing whether the skin prick test results actually agree or correlate with reality (Berkow, pg. 650, paragraph 4). **Conversely, the applicant's method can identify an allergen without the skin prick test.** The applicant's Claim 1 specifically recites "computing a plurality of correlations corresponding to the plurality of possible influencing agents as each of the plurality of possible influencing agents relate to the reaction; and based on the plurality of correlations, identifying and displaying the suspect influencing agent." Neither Berkow nor Evans discloses these steps of the applicant's invention as claimed. If they were to suggest the applicant's invention (which they don't), there would be no reason to suggest the use of a skin prick test (which they do).
- Regarding Claim 1, Berkow in some cases appears to identify an allergen by way of an elimination diet (Berkow, pg. 329, paragraph 6). Elimination diets are very old and do not require "computing a plurality of correlations," as specifically recited in Claim 1. Neither Berkow nor Evans discloses this step of the applicant's invention. If they were to suggest the applicant's invention (which they

don't), there would be no reason to suggest the use of an elimination diet (which they do).

- Regarding Claim 1, Evans appears to disclose a computerized method of checking a patient's medical record for already-known allergies, but the method does not appear to determine or discover an unknown allergy. Neither Evans nor Berkow appear to suggest any computerized way of determining a suspect influencing agent as defined in Claim 1.
- Regarding Claim 1, the Examiner states "Berkow also teaches that patterns of symptoms may be correlated to environmental exposure....," but the applicant cannot find where Berkow says this. On pg. 650, paragraph 4, Berkow actually says, "results are correlated with the pattern of symptoms and related to environmental exposures." Berkow's statement is a little confusing, but it appears that Berkow is saying that the results are correlated with the pattern of symptoms, and the results are related to environmental exposures. The applicant is having difficulty making sense of this, but the fact that Berkow clearly states "the results are correlated with the pattern of symptoms" appears to mean the test results and the symptoms are compared for correlation, whereas in the case of the applicant's invention, the exposures and the symptoms are compared for correlation. The difference being: Berkow uses the skin prick test, and the applicant does not.
- Regarding Claim 2, the applicant has incorporated that claim into Claim 1. The Examiner states "Berkow teaches that a plurality of symptoms is correlated to a plurality of possible causes." On page 650, paragraph 4, Berkow actually says, "...results are correlated with the pattern of symptoms..." The applicant's remarks in the preceding paragraph pertaining to Claim 1 applies to Claim 2 as well.
- Regarding Claim 3, the Examiner states that the Evans program is capable of sorting data. Claim 3, however, specifically recites, "sorting the plurality of possible influencing agents based on the plurality of correlations." Such a sorting

scheme provides a way of readily identifying the suspect influencing agent. Evans fails to disclose or suggest such a sorting scheme.

- Regarding Claim 4, the applicant's step of adding an additional possible influencing agent is not necessarily an influencing agent designated for a particular period.
- Regarding Claim 7, the Examiner states, "Berkow does not explicitly disclose entering additional symptoms; however, Berkow discloses monitoring the recrudescence of symptoms." The applicant asserts that Claim 7 specifically recites, "entering a plurality of reactions into the computer," which is not the same as monitoring the recrudescence of symptoms.
- Regarding Claim 12, Berkow refers to a correlation that pertains to a skin prick test, but the applicant's invention does not require any skin prick test, thus Berkow's so-called correlation is not the same as the applicant's claimed "plurality of correlations."
- Regarding Claim 14, the Examiner states that Berkow discloses that the influencing agent may be a foodstuff. The applicant, however, is not claiming to be the first to recognize food as being a possible influencing agent. Rather, the applicant is claiming a novel method that can identify various types of influencing agents, including food.
- Regarding Claim 15, the Examiner states that Berkow discloses that ingredients in foods may cause reactions. The applicant, however, notes that Berkow fails to disclose "computing a correlation between the ingredient and the reaction," as specifically recited in Claim 15.
- Regarding Claim 16, the Examiner states that Berkow discloses that symptom occurs some time after the food is ingested. The applicant, however, asserts that Berkow fails to disclose, "computing a time-delayed correlation between the suspect influencing agent and the reaction," as specifically recited in Claim 16.

- Regarding Claim 17, the Examiner states that Evans discloses determining 95 percent confidence interval. The applicant believes the 95 percent confidence interval pertains to the effectiveness of implementing Evans' computerized program, not the confidence of a correlation value. Neither Berkow nor Evans suggests assigning a plurality of confidence values to a plurality of correlations, as specifically recited by the applicant in Claim 17.
- Regarding Claim 18, although Berkow suggests an elimination diet that can change from one day to the next. In doing so, Berkow can determine if some diets are better than others. Berkow fails to disclose calculating a plurality of reaction/agent correlations on foods that are intermittently consumed (on and off) over a span of multiple days. The applicant's invention, however, allows this to be accomplished.
- Regarding Claim 19, Berkow and many others certainly acknowledge that food can be allergens. Berkow and others, however, fail to pick out an allergen among numerous possible influencing agents based on equally numerous reaction/agent correlations.
- Regarding Claim 20, Berkow and others certainly acknowledge the existence of adverse environmental exposures. Berkow and others, however, fail to pick out an environmental exposure among numerous possible influencing agents based on numerous reaction/agent correlations. The correlation that Berkow refers to pertains to the validity of a skin prick test.
- Regarding Claim 21, Berkow might teach that reactions can be associated with pain, however, Berkow fails to identify a likely cause of a pain-related reaction by computing numerous reaction/agent correlations of numerous possible influencing agents.
- Regarding Claim 22, Berkow might teach that food additives can cause asthma or other respiratory-related reactions, however, Berkow fails to identify a likely cause of a respiratory-related reaction by computing numerous reaction/agent correlations of numerous possible influencing agents.

- Regarding Claim 23, Berkow might teach that food can cause perianal eczema or other skin-related reactions, however, Berkow fails to identify a likely cause of a skin-related reaction by computing numerous reaction/agent correlations of numerous possible influencing agents.
- Regarding Claim 24, Berkow might teach that food can cause high blood pressure, however, Berkow fails to specifically identify a likely cause of high blood pressure by computing numerous reaction/agent correlations of numerous possible influencing agents.
- Regarding Claim 25, Berkow might teach that food can cause fatigue, however, Berkow fails to specifically identify a likely cause of the fatigue by computing numerous reaction/agent correlations of numerous possible influencing agents.
- Regarding Claims 26 and 28, Berkow might teach that food can cause mentally-related problems or emotional disturbances, however, Berkow fails to specifically identify a likely cause of such problems by computing numerous reaction/agent correlations of numerous possible influencing agents.
- Regarding Claim 27, Berkow might teach that an allergy could bring on convulsions, however, Berkow fails to identify what specifically might be causing a seizure by computing numerous reaction/agent correlations of numerous possible influencing agents.
- Regarding Claim 29, Berkow might teach that food can cause an allergic reaction, but Berkow does not suggest that the actual act of eating can cause a reaction. The applicant has amended Claim 29 to clarify this point.

Claims 5, 6, 8 and 32 have been rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERCK MANUAL in view of Evans et al., A COMPUTER ASSISTED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 and further in view of

Rappaport et. al. (4,752,889). The applicant, however, disagrees with the rejection for the following reasons:

- Regarding Claim 5, Neither Berkow nor Evans suggest any reason or motivation for using a computer to select first and second pluralities of influencing agents. Berkow teaches skin prick testing and elimination diets. Evans discloses a computerized medical record that looks for errors. Rappaport discloses general mouse-clicking. These three references are distinctly different from each other and their combination is awkward and disjointed. Nonetheless, even if these references are combined, they still fail to disclose the applicant's invention as claimed.
- Regarding Claim 6, the Examiner has not pointed out where Berkow or Evans suggests the applicant's step of selecting a reaction.
- Regarding Claim 8, none of the cited references suggest displaying a single view of the reaction and the plurality of possible influencing agents, as claimed by the applicant
- Regarding Claim 32, the Examiner states that Claim 32 repeats the limitations of Claims 1 and 4 – 6, cumulatively, and is therefore rejected for the same reasons. Claim 32, however, also includes the limitations of original Claim 2. Thus, applicant submits that Claim 32 should be allowed for reasons already presented with reference to Claims 1, 2, and 4 – 6.

Claim 9 is rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Kadtke et al. (6,401,057). The Examiner states that Figure 2B of Kadtke discloses graphing of a correlation parameter versus time delay and that it would have been obvious to generate and display the graph of the correlation versus time delay. The applicant, however, disagrees with the rejection for the following reason.



- Regarding Claim 9, the applicant isn't claiming simply the graphing of a correlation parameter versus time delay. Rather, the applicant claims plotting the **suspect influencing agent AND the reaction** versus time.

Claims 10 and 11 are rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Small et al. (5,910,421). The Examiner states that Small teaches that magnitude values may be assigned to data points and that it would have been obvious to assign magnitude values to the reaction or to the plurality of influencing agents. The applicant, however, disagrees with the rejection for the following reason:

- Regarding Claims 10 and 11, none of the cited references disclose or suggest any reason or motivation to assign magnitude values to reactions or influencing agents as claimed by the applicant.

Claim 13 is rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Lowy, MEDICAL PROGRESS: STAPHYLOCOCCUS AUREUS INFECTIONS. The Examiner states that it would have been obvious to consider the menstruation cycle, as taught by Lowy, when implementing the automated allergy diagnostic system as jointly taught by Berkow and Evans. The applicant, however, disagrees with the rejection for the following reason:

- Regarding Claim 13, this claim covers the concept of selectively considering or disregarding data collected during a menstrual cycle. This feature can be useful in cases where a menstrual period might alter a woman's usual reaction to an influencing agent. None of the cited art seems to recognize this problem or suggest such a solution.

Claim 30 is rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Mebane (5,486,999). The Examiner states that it would have been obvious to identify sleep as a possible influencing agent, as taught by Mebane, when implementing the automated allergy diagnostic system as jointly taught by Berkow and Evans. The applicant, however, disagrees with the rejection for the following reason:

- Regarding Claim 30, the Examiner states that Mebane teaches that the amount of sleep the patient has may be screened as factors that affect patient care. That might be true, but the applicant is not claiming that.

Claim 31 is rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS as applied to Claim 1 above and further in view of Teller (2002/0013538). The Examiner states that it would have been obvious to correlate patient symptoms with locale-specific environmental data, as taught by Teller, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans. The applicant, however, disagrees with the rejection for the following reason:

- Regarding Claim 31, the applicant has amended the claim to more distinctly specify that the computed correlation can be used to help determine the suspect influencing agent rather than just to explain why an individual's known asthma condition is acting up.

Claim 33 is rejected under 35 USC 103(a) as being unpatentable over Berkow et al., THE MERK MANUAL in view of Evans et al., A COMPUTER ASSITED

MANAGEMENT PROGRAM FOR ANTIBIOTICS AND OTHER ANTIINFECTIVE AGENTS, Rappaport et al. (4,752,889), Kadtke et al. (6,401,057), and Small et al. (5,910,421). The Examiner states that Claim 33 repeats the limitations of Claims 1, 3-6, 9, 10, 12 and 14 cumulatively, and is therefore rejected for the same reasons, and incorporated herein.

- Regarding Claim 33, the Examiner states that Claim 33 repeats the limitations of Claims 1, 3-6, 9, 10, 12 and 14, cumulatively, and is therefore rejected for the same reasons. Claim 33, however, also includes the limitations of original Claim 2. Thus, applicant submits that Claim 33 should be allowed for reasons already presented with reference to Claims 1-6, 9, 10, 12 and 14.

For the above-listed reasons, the applicant submits that Claims 1 and 3 - 33 are neither anticipated nor obvious in view of the cited art. Thus, the Examiner is respectfully requested to enter the amendments and allow Claims 1 and 3 - 33.

Respectfully submitted,



Robert J. Harter (Reg: 32,031)  
Patent Agent for Applicant  
608-519-1400